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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BRYAN CAVE POWELL GOLDSTEIN
ONE ATLANTIC CENTER FOURTEENTH FLOOR
1201 WEST PEACHTREE STREET NW
ATLANTA, GA 30309-3488

EXAMINER	
PEPITONE, MICHAEL F	

ART UNIT	PAPER NUMBER
1796	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,797	GEROLD ET AL.	
	Examiner	Art Unit	
	MICHAEL PEPITONE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7-9,11-18 and 20-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7-9,11-18 and 20-22* is/are rejected.

7)☒ Claim(s) *1,11,12 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/4/09 has been entered.

Claim Objections

Claims 1, 11-12, and 20 are objected to because of the following informalities: Multiple periods in the claims (See Fressola v. Manbeck, 36 USPQ2d 1211 (D.D.C. 1995) [MPEP 608.01(m)]. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7-9, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Heath (US 5,725,570).

Regarding claims 1-3, 5, 7-9, and 16-18: Heath teaches a radiopaque stent filament (8:30-49) having an outer core of a superelastic alloy (NiTi alloy {nitinol}) {base component} and an inner core of a radiopaque element (tantalum) (7:31-49); wherein the filament is prepared by boring a 0.25" hole in a 0.75" diameter nitinol rod, and providing a tantalum rod of substantially matched outer diameter of the bored hole (~0.25") for placement within the nitinol rod; affording a rod {prior to forging into a filament} (8:30-49) containing about 77 wt% nitinol and about 24 wt% tantalum {as calculated by examiner: assume 12" length; 0.75" od nitinol rod with 0.25" id = volume of 77.22 cm^3; tantalum rod with 0.25" od = volume of 9.65 cm^3; ρ nitinol = 6.5 g/cm^3; ρ tantalum = 16.6 g/cm^3; 501.93 g nitinol and 160.19 g tantalum contained in the two part rod = 76 wt% nitinol and 24 wt% tantalum}. Substituting a copper-zinc -aluminum alloy (7:1-30) {ρ CuZnAl = 7.6 g/cm^3) for nitinol affords 79 wt% CuZnAl and 21 wt% Ta [instant claims 1-3, 5, 9, 18].

Preferred filaments include NiTi/Ta filaments having 0.008" od and 0.00195" id (9:46-52) yielding 62 wt% NiTi and 38 wt% Ta [instant claims 1-2, 5, 7-9, 17-18]. Heath discloses additional radiopaque materials {core materials} such as iridium (7:31-49) (ρ Ir = 22.4 g/cm^3). Substituting Ir for Ta affords a stent filament containing 56 wt% NiTi and 44 wt% Ir [instant claim 16]. Substituting a copper-zinc -aluminum alloy (7:1-30) {ρ CuZnAl = 7.6 g/cm^3) for nitinol affords 79 wt% CuZnAl and 21 wt% Ta [instant claim 3].

Claims 11 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Heath (US 5,725,570).

Regarding claim 11: Heath teaches a radiopaque stent filament (8:30-49; 9:37-46) having an outer core of a superelastic alloy (NiTi alloy {nitinol}) {base component} and an inner core of a radiopaque element (tantalum) (7:31-49); wherein the filament is prepared by boring a 0.25" hole in a 0.75" diameter nitinol rod, and providing a tantalum rod of substantially matched outer diameter of the bored hole (~0.25") for placement within the nitinol rod; affording a rod {prior to forging into a filament} (8:30-49) containing about 77 wt% nitinol and about 24 wt% tantalum {as calculated by examiner: assume 12" length; 0.75" od nitinol rod with 0.25" id = volume of 77.22 cm^3; tantalum rod with 0.25" od = volume of 9.65 cm^3; ρ nitinol = 6.5 g/cm^3; ρ tantalum = 16.6 g/cm^3; 501.93 g nitinol and 160.19 g tantalum contained in the rod = 76 wt% nitinol and 24 wt% tantalum}. Substituting a copper-zinc -aluminum alloy (7:1-30) {ρ CuZnAl = 7.6 g/cm^3) for nitinol affords 79 wt% CuZnAl and 21 wt% Ta.

Preferred filaments include NiTi/Ta filaments having 0.008" od and 0.00195" id (9:46-52) yielding 62 wt% NiTi and 38 wt% Ta [instant claim 11]. Heath discloses additional radiopaque materials {core materials} such as iridium (7:31-49) (ρ Ir = 22.4 g/cm^3). Substituting Ir for Ta affords a stent filament containing 56 wt% NiTi and 44 wt% Ir. Substituting a copper-zinc -aluminum alloy (7:1-30) {ρ CuZnAl = 7.6 g/cm^3) for nitinol affords 79 wt% CuZnAl and 21 wt% Ta.

Regarding claim 14: Heath teaches aortic stents {endovascular implant} (5:36-39).

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Heath (US 5,725,570).

Regarding claim 12: Heath teaches a radiopaque stent filament (8:30-49; 9:37-46) having an outer core of a superelastic alloy (NiTi alloy {nitinol}) {base component} and an inner core of a radiopaque element (tantalum) (7:31-49); wherein the filament is prepared by boring a 0.25" hole in a 0.75" diameter nitinol rod, and providing a tantalum rod of substantially matched outer diameter of the bored hole (~0.25") for placement within the nitinol rod; affording a rod {prior to forging into a filament} (8:30-49) containing about 77 wt% nitinol and about 24 wt% tantalum {as calculated by examiner: assume 12" length; 0.75" od nitinol rod with 0.25" id = volume of 77.22 cm^3; tantalum rod with 0.25" od = volume of 9.65 cm^3; ρ nitinol = 6.5 g/cm^3; ρ tantalum = 16.6 g/cm^3; 501.93 g nitinol and 160.19 g tantalum contained in the rod = 76 wt% nitinol and 24 wt% tantalum}. Substituting a copper-zinc -aluminum alloy (7:1-30) {ρ CuZnAl = 7.6 g/cm^3) for nitinol affords 79 wt% CuZnAl and 21 wt% Ta [instant claim 12].

Preferred filaments include NiTi/Ta filaments having 0.008" od and 0.00195" id (9:46-52) yielding 62 wt% NiTi and 38 wt% Ta [instant claims 12]. Heath discloses additional radiopaque materials {core materials} such as iridium (7:31-49) (ρ Ir = 22.4 g/cm^3). Substituting Ir for Ta affords a stent filament containing 56 wt% NiTi and 44 wt% Ir. Substituting a copper-zinc -aluminum alloy (7:1-30) {ρ CuZnAl = 7.6 g/cm^3) for nitinol affords 79 wt% CuZnAl and 21 wt% Ta.

Claim 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Heath (US 5,725,570).

Regarding claims 20-21: Heath teaches a radiopaque stent filament (8:30-49; 9:37-46) having an outer core of a superelastic alloy (NiTi alloy {nitinol}) {base component} and an inner

core of a radiopaque element (tantalum) (7:31-49); wherein the filament is prepared by boring a 0.25" hole in a 0.75" diameter nitinol rod, and providing a tantalum rod of substantially matched outer diameter of the bored hole (~0.25") for placement within the nitinol rod; affording a rod {prior to forging into a filament} (8:30-49) containing about 77 wt% nitinol and about 24 wt% tantalum {as calculated by examiner: assume 12" length; 0.75" od nitinol rod with 0.25" id = volume of 77.22 cm^3; tantalum rod with 0.25" od = volume of 9.65 cm^3; ρ nitinol = 6.5 g/cm^3; ρ tantalum = 16.6 g/cm^3; 501.93 g nitinol and 160.19 g tantalum contained in the rod = 76 wt% nitinol and 24 wt% tantalum}. Substituting a copper-zinc -aluminum alloy (7:1-30) {ρ CuZnAl = 7.6 g/cm^3) for nitinol affords 79 wt% CuZnAl and 21 wt% Ta [instant claims 20-21].

Preferred filaments include NiTi/Ta filaments having 0.008" od and 0.00195" id (9:46-52) yielding 62 wt% NiTi and 38 wt% Ta [instant claims 1-2, 5, 7-9]. Heath discloses additional radiopaque materials {core materials} such as iridium (7:31-49) (ρ Ir = 22.4 g/cm^3). Substituting Ir for Ta affords a stent filament containing 56 wt% NiTi and 44 wt% Ir. Substituting a copper-zinc -aluminum alloy (7:1-30) {ρ CuZnAl = 7.6 g/cm^3) for nitinol affords 79 wt% CuZnAl and 21 wt% Ta.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Lindenberg *et al.* (WO 02/100452). Meyer-Lindenberg *et al.* (US 2004/0241036) was used as the English translation.

Regarding claim 11 and 13: Meyer-Lindenberg *et al.* teaches a medical implant (¶ 1,18-21) made from a magnesium alloy containing lithium and rare earth metals (¶ 6-16, 23); preferred embodiments contain 0.01 to 7 mass% lithium, 0.01 to 16 mass% aluminum, 0.01 to 7 mass% yttrium and 0.01 to 8 mass% rare earth metals (¶ 10-17, 30). The preferred embodiment is the magnesium alloy MgY4RE3Li2.4 {4 mass% yttrium, 3 mass% rare earth {Ce}, 2.4 mass% lithium, and remainder (90.6 mass%) magnesium (corresponding to 93 mass% base and 7 mass% radiopaque {Y and Ce}).

Meyer-Lindenberg *et al.* does not specifically teach an embodiment containing 10 to 90 wt% of a base alloy and 10 to 90 wt% radiopaque elements. However Meyer-Lindenberg *et al.* teaches magnesium alloys could contain up to 7 mass% Y and 8 mass% RE {Ce} {radiopaque materials} (¶ 9-14) for a total of up to 15 mass% radiopaque materials {remainder 0.01 to 7 mass% lithium, 0.01 to 16 mass% aluminum, and magnesium (¶ 10-17, 30) [instant claims 11

and 13]. At the time of invention a person of ordinary skill in the art would have found it obvious to have made a radiopaque medical magnesium alloy medical implant containing up to 15 mass% radiopaque materials based on the invention of Meyer-Lindenberg *et al.*, and would have been motivated to do so since Meyer-Lindenberg *et al.* suggests that such alloys are preferred for the construction of biodegradable magnesium alloy medical implants (¶ 6, 10-17, 18-23).

Regarding claim 14: Meyer-Lindenberg *et al.* teaches bone screws {orthopedic implants} (¶ 1, 18-21).

Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Lindenberg *et al.* (WO 02/100452). Meyer-Lindenberg *et al.* (US 2004/0241036) was used as the English translation.

Regarding claim 12 and 15: Meyer-Lindenberg *et al.* teaches a medical implant (¶ 1,18-21) made from a biodegradable magnesium alloy containing lithium and rare earth metals (¶ 6-16, 23); preferred embodiments contain 0.01 to 7 mass% lithium, 0.01 to 16 mass% aluminum, 0.01 to 7 mass% yttrium and 0.01 to 8 mass% rare earth metals (¶ 10-17, 30). While the preferred embodiment is the magnesium alloy MgY4RE3Li2.4 {4 mass% yttrium, 3 mass% rare earth {Ce}, 2.4 mass% lithium, and remainder (90.6 mass%) magnesium (corresponding to 93 mass% base and 7 mass% radiopaque {Y and Ce}).

Meyer-Lindenberg *et al.* does not specifically teach an embodiment containing 10 to 90 wt% of a base alloy and 10 to 90 wt% radiopaque elements. However Meyer-Lindenberg *et al.* teaches magnesium alloys could contain up to 7 mass% Y and 8 mass% RE {Ce} {radiopaque

materials} (¶ 9-14) for a total of up to 15 mass% radiopaque materials {remainder 0.01 to 7 mass% lithium, 0.01 to 16 mass% aluminum, and magnesium (¶ 10-17, 30) [instant claims 12 and 15]. At the time of invention a person of ordinary skill in the art would have found it obvious to have made a radiopaque medical magnesium alloy medical implant containing up to 15 mass% radiopaque materials based on the invention of Meyer-Lindenberg *et al.*, and would have been motivated to do so since Meyer-Lindenberg *et al.* suggests that such alloys are preferred for the construction of biodegradable magnesium alloy medical implants (¶ 6, 10-17, 18-23).

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Lindenberg *et al.* (WO 02/100452). Meyer-Lindenberg *et al.* (US 2004/0241036) was used as the English translation.

Regarding claim 20: Meyer-Lindenberg *et al.* teaches a medical implant (¶ 1,18-21) made from a biodegradable magnesium alloy containing lithium and rare earth metals (¶ 6-16, 23); preferred embodiments contain 0.01 to 7 mass% lithium, 0.01 to 16 mass% aluminum, 0.01 to 7 mass% yttrium and 0.01 to 8 mass% rare earth metals (¶ 10-17, 30). While the preferred embodiment is the magnesium alloy MgY4RE3Li2.4 {4 mass% yttrium, 3 mass% rare earth {Ce}, 2.4 mass% lithium, and remainder (90.6 mass%) magnesium (corresponding to 93 mass% base and 7 mass% radiopaque {Y and Ce}).

Meyer-Lindenberg *et al.* does not specifically teach an embodiment containing 10 to 90 wt% of a base alloy and 10 to 90 wt% radiopaque elements. However Meyer-Lindenberg *et al.* teaches magnesium alloys could contain up to 7 mass% Y and 8 mass% RE {Ce} {radiopaque

materials} (¶ 9-14) for a total of up to 15 mass% radiopaque materials {remainder 0.01 to 7 mass% lithium, 0.01 to 16 mass% aluminum, and magnesium (¶ 10-17, 30) [instant claim 20]. At the time of invention a person of ordinary skill in the art would have found it obvious to have made a radiopaque medical magnesium alloy medical implant containing up to 15 mass% radiopaque materials based on the invention of Meyer-Lindenberg *et al.*, and would have been motivated to do so since Meyer-Lindenberg *et al.* suggests that such alloys are preferred for the construction of biodegradable magnesium alloy medical implants (¶ 6, 10-17, 18-23).

Regarding claim 21: Meyer-Lindenberg *et al.* teaches bone screws (¶ 1, 18-21).

Claims 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Lindenberg *et al.* (WO 02/100452), as applied to claim 20 above, when taken with Gellman *et al.* (US 2003/0199993). Meyer-Lindenberg *et al.* (US 2004/0241036) was used as the English translation.

Regarding claim 22: Meyer-Lindenberg *et al.* teaches the basic claimed implant [as set forth above with respect to claim 20], wherein bone implants are coated with the magnesium alloy (¶ 1, 18-21).

Gellman *et al.* (US '993) provides evidence for porous bone implants {bone anchors, plates, rods} (¶ 24, 38).

The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. See attached form PTO-892.

Response to Arguments

Applicant's arguments filed with the amendment entered with the RCE have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MFP
8-April-09

/Harold Y Pyon/
Supervisory Patent Examiner, Art Unit 1796